UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN LOSARTAN AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider **Jury Trial Demanded** **First Amended Consolidated Irbesartan Class Action Complaint**

FIRST AMENDED CONSOLIDATED IRBESARTAN CLASS ACTION COMPLAINT

1. COME NOW, the Consumer and Third Party Payor ("TPP") Plaintiffs (collectively the "Class Plaintiffs"), who file this First Amended Consolidated Irbesartan Economic Loss Class Action Complaint ("Master Irbesartan Class Complaint")[1] against the below-enumerated Defendants.

I. INTRODUCTION

2. This case arises from adulterated, misbranded, and unapproved irbesartan-containing drugs ("ICDs") that were designed, manufactured, marketed, distributed, packaged, and sold by Defendants in the United States, and which have been and remain the subject of one of the largest ongoing contaminated drug recalls ever in the United States. These ICDs are non-merchantable, and are not of the quality represented by Defendants named herein.

3. Irbesartan and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Avapro® and Avalide®, respectively. These RLDs are

[1] This is one of two irbesartan master complaints being filed in this multi-district litigation. The filing of three master complaints is to streamline the pleadings and issues for the parties' mutual convenience only. Consumer Class Plaintiffs do not waive any claims that are not raised herein, or that are asserted in another master complaint.

indicated for, *inter alia*, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association.[2] Several million U.S. patients pay for (in whole or in part) and consume generic valsartan each year.

4. The Class Plaintiffs bring this economic-loss action on behalf of ICD consumers and third-party payors who paid or made reimbursements for Defendants' adulterated, misbranded, and/or unapproved ICDs illegally manufactured, sold, labeled, marketed, and distributed in the United States as FDA-approved generic versions of Avapro® and Avalide®. Defendants' generic ICDs were in fact not FDA-approved generic versions of these drugs, and were instead of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with IARC- and EPA-listed probable human carcinogen known as N-nitrosodiethylamine ("NDEA").

5. Beginning in January of 2019 and continuing through March of 2020, the United States Food & Drug Administration ("FDA") announced recalls of Defendants' ICDs due to levels of NDEA that exceed acceptable levels set by the FDA.

6. Defendants have been illegally manufacturing, selling, labeling, marketing and distributing the misbranded and/or adulterated ICDs in the United States for years, reaping many millions of dollars in profit, while not disclosing to Class Plaintiffs the true nature of the ICDs.

7. At all times during the period alleged herein, Defendants represented and warranted to consumers and TPPs that their generic ICDs were therapeutically equivalent to and otherwise the same as their RLDs, were fit for their ordinary uses, and were manufactured and distributed in accordance with applicable laws and regulations.

[2] https://www.heart.org/en/news/2018/05/01/more-than-100-million-americans-have-high-blood-pressure-aha-says (last accessed June 5, 2019).

8. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic ICDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded ICDs for purchase and reimbursement in the United States by U.S. consumers and TPPs.

9. The Class Plaintiffs paid for or made reimbursements for generic ICDs that were illegally and willfully introduced into the market by Defendants, causing the Plaintiff Class(es) to sustain economic damages. Defendants' generic ICDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law as set forth herein.

10. The ICDs Defendants sold to Class Plaintiffs were worthless due to the presence of nitrosamines which rendered the ICDs unfit for use and for human consumption, requiring recall by the FDA. Class Plaintiffs would not have purchased the ICDs had they known the true nature of the ICDs.

11. Further, Class Plaintiffs suffered injury in having to purchase replacement medications, while not receiving the full benefit of the ICDs they purchased. Specifically, Class Plaintiffs were required to cease using ICDs they had paid for and repurchase a replacement medication. Had the ICDs been properly manufactured, Class Plaintiffs would have received the benefit of the full bottle of the product they purchased and would not have incurred the cost of paying for replacement medication.

II. PARTIES

A. Consumer Class Representatives

12. Plaintiff N. Albert Bacharach Jr. is a Florida resident and citizen. During the class period, Plaintiff Bacharach Jr. paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the ZHP Defendants (as defined infra Part III.). Plaintiff Bacharach Jr. purchased ICDs manufactured by Defendants ZHP, Prinston and Solco, and sold by Walgreens. Defendants expressly and impliedly warranted to Plaintiff Bacharach Jr. that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Bacharach Jr. purchased a product that was not the same as the RLD. When purchasing his ICDs from Defendants, Plaintiff Bacharach Jr. reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Bacharach Jr. relied on these representations and warranties in deciding to purchase his ICDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Bacharach Jr. known the product was not the same as the RLD, Plaintiff Bacharach Jr. would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Bacharach Jr. would not have paid for Defendants' ICDs.

13. Plaintiff Ronald Annis is a Florida resident and citizen. During the class period, Plaintiff Annis paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the ZHP Defendants (as defined infra Part III.). Plaintiff Annis was prescribed ICDs manufactured and distributed by Defendants ZHP and Solco, which

he purchased from a Walgreens pharmacy in St. Petersburg, Florida. Plaintiff Annis purchased Defendants' recalled and contaminated ICDs on at least four occasions. Each time, Plaintiff received ICDs from Defendants bearing the NDC number 43547-376-09, a 300 mg dose. Plaintiff paid co-pays of $8.70 each time for the medication. Defendants expressly and impliedly warranted to Plaintiff Annis that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Annis purchased a product that was not the same as the RLD. When purchasing his ICDs from Defendants, Plaintiff Annis reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Annis relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Annis known the product was not the same as the RLD, Plaintiff Annis would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Annis would not have paid for Defendants' ICDs.

14. Plaintiff Brian Wineinger is an Indiana resident and citizen. During the class period, Plaintiff Wineinger paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Wineinger was prescribed ICDs manufactured and distributed by Defendants ZHP, Prinston and Solco, which he purchased from Walmart in Avon, Indiana. Plaintiff Wineinger purchased Defendants' recalled and contaminated ICDs on at least six occasions. Plaintiff Wineinger received irbesartan medication bearing the NDC number 43547-376-09, a 300 mg dose. Each time, Plaintiff Wineinger paid a co-pay of $9.00 or $10.00. After hearing about the

recall, Plaintiff Wineinger cross referenced the affected NDC numbers with the NDC numbers of the medications he purchased, and determined that he was prescribed, purchased, and had been consuming the contaminated ICDs manufactured by Solco and Prinston. Plaintiff Wineinger called his pharmacy, whose employee confirmed that he had purchased and was consuming recalled, contaminated medication. Plaintiff Wineinger ceased using the medication before finishing each of the pills from the last fill, and had to purchase replacement medication. On February 1, 2019, Plaintiff Wineinger received a recall letter from his insurance company, identifying his medication as subject to the recall. Defendants expressly and impliedly warranted to Plaintiff Wineinger that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Wineinger purchased a product that was not the same as the RLD. When purchasing his ICDs from Defendants, Plaintiff Wineinger reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Wineinger relied on these representations and warranties in deciding to purchase his ICDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Wineinger known the product was not the same as the RLD, Plaintiff Wineinger would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Wineinger would not have paid for Defendants' ICDs.

15. Plaintiff Michael Johnson is a New York resident and citizen. During the class period, Plaintiff Johnson paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the ZHP Defendants (as defined infra Part III.). Plaintiff

Johnson was prescribed ICDs manufactured and distributed by Defendants, which he purchased from a Wegman's supermarket in Penfield, New York. Plaintiff Johnson purchased Defendants' recalled and contaminated ICDs on at least three occasions. Each time, Plaintiff received irbesartan medication from Defendants bearing the NDC number 43547-376-09, a 300 mg dose. Plaintiff paid co-pays of $14.78, $15.47, and $14.89 for the medication. After purchasing the medication, on January 30, 2019, Plaintiff received a recall letter from his insurance company, identifying his medication as subject to the recall. The recall letter instructed him to contact his doctor to discuss alternative treatment options. Defendants expressly and impliedly warranted to Plaintiff Johnson that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Johnson purchased a product that was not the same as the RLD. When purchasing his ICDs from Defendants, Plaintiff Johnson reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Johnson relied on these representations and warranties in deciding to purchase his ICDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Johnson known the product was not the same as the RLD, Plaintiff Johnson would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Johnson would not have paid for Defendants' ICDs.

16. Plaintiff Rachel Miller is a Maryland resident and citizen. During the class period, Plaintiff Miller paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the ZHP Defendants (as defined infra Part III.). Specifically, Plaintiff Miller purchased recalled and contaminated ICDs manufactured by ZHP,

Prinston and Solco. Ms. Miller purchased her medication through Aetna Rx Home Delivery, LLC. Defendants expressly and impliedly warranted to Plaintiff Miller that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Miller purchased a product that was not the same as the RLD. When purchasing her ICDs from Defendants, Plaintiff Miller reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Miller relied on these representations and warranties in deciding to purchase her ICDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Miller known the product was not the same as the RLD, Plaintiff Miller would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Miller would not have paid for Defendants' ICDs.

17. Plaintiff Charmaine Westry is an Alabama resident and citizen. During the class period, Plaintiff Westry paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by the ZHP Defendants (as defined infra Part III.). Plaintiff Westry was prescribed irbesartan-containing medication manufactured and distributed by Defendants ZHP, Solco and Prinston, which she purchased from Sam's Club/Walmart in Saraland, Alabama. Specifically, Plaintiff purchased now recalled irbesartan medication from Defendants bearing the NDC number 43547-376-09, a 300 mg dose. Plaintiff paid a co-pay of $24.00 for the medication. After purchasing the medication, on January 21, 2019, Plaintiff received a recall letter from her pharmacy, identifying her medication as subject to the recall. Defendants expressly and impliedly warranted to Plaintiff Westry that their respective generic

ICDs were the same as their RLDs. But in fact, Plaintiff Westry purchased a product that was not the same as the RLD. When purchasing her ICDs from Defendants, Plaintiff Westry reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Westry relied on these representations and warranties in deciding to purchase her ICDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Westry known the product was not the same as the RLD, Plaintiff Westry would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Westry would not have paid for Defendants' ICDs.

B. The Third Party Payor ("TPP") Class Representatives

18. Plaintiff MSP Recovery Claims, Series LLC ("MSPRC") is a Delaware series limited liability company with its principal place of business in Coral Gables, Florida. MSPRC's limited liability company agreement provides for the establishment of one or more specific series. All records of all series are maintained together with all assets of MSPRC.

19. As detailed below, certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to series LLCs of MSPRC. Pursuant to MSPRC's limited liability agreement, all rights arising from the assignment to its series (including the assignments discussed below), along with the right to bring any lawsuit in connection with that assignment (including those below), belong to MSPRC. As such, MSPRC has the right and power to sue defendants to recover the payments at issue in this action.

20. Certain series of MSPRC have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assignors' health plan members and enrollees. These assignments authorize the series and, in turn MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. MSPRC alleges the assignments at issue below.

21. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC. Specifically, the assignments provide the following:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

22. On May 12, 2017, Summacare, Inc. ("Summacare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC ("MSP Recovery"). Specifically, the assignment provides the following language:

> [Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers

> and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

23. On June 12, 2017, MSP Recovery irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery] . . . .

24. Summarcare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery to Series 16-11-509, which is memorialized in a letter dated September 5, 2018.

25. On March 20, 2018, Connecticare, Inc. ("Connecticare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC. Specifically, the assignment provides the following language:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

26. MSPRC is only asserting claims based on the above assignments. Collectively, Emblem, Connecticare, and Summacare shall be referred to as the "Assignors."

27. Defendants have manufactured and distributed the ICDs throughout the United States, for which consumers made co-payments, and TPPs paid. Specifically, the Assignors paid for ICDs

listed as recalled by the United States Food and Drug Administration and that were manufactured, distributed, or sold by the Defendants.

28. Plaintiff Maine Automobile Dealers Association, Inc. Insurance Trust is a duly organized and existing 501(c)(9) tax-exempt trust that qualifies as a multiple employer welfare benefit plan or arrangement established or maintained for the purpose of offering or providing health benefits, including prescription drug coverage, to the employees of multiple employers and to their beneficiaries under the authority of the Maine Multiple-Employer Welfare Arrangements law, Title 24-A, Chapter 81, §§ 6601-6616 of the Maine Revised Statutes Annotated and the Employee Retirement Income Security Act of 1974. The Trust was organized in Maine and has its principal place of business in Maine.

29. The Trust administers a multiple-employer welfare arrangement for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance.

30. The Trust provides health benefit coverage, including a prescription drug benefit, to its members. The Trust's members received prescriptions for and it paid for ICDs listed as recalled by the United States Food and Drug Administration and that were manufactured, distributed, or sold by Defendants (as defined *infra* Part II.C).

C. Defendants

31. Defendants are comprised of entities at various points in the manufacture, labeling, packaging, and distribution chain.

32. Defendants comprise various levels of the distribution chain, beginning with the highest level, the active pharmaceutical ingredient ("API") level. Generally, the irbesartan API is manufactured and sold to finished-dose manufacturers, who then distribute the finished product

to labelers/distributors, as well as repackagers, who then distribute and sell the ICDs to pharmacy retailers. Pharmacy retailers then sell the ICDs the consumers, including the Class Plaintiffs.

i. Zhejiang Huahai Pharmaceutical Co., Ltd and Related Defendants

33. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The company also has a United States headquarters located at 2009 and 2002 Eastpark Blvd., Cranbury, NJ 08512. ZHP on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, ZHP has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic ICDs throughout the United States. ZHP is the parent company of subsidiaries Prinston Pharmaceutical Inc., Solco Healthcare, LLC, and Huahai U.S., Inc. The ICDs made by Zhejiang Huahai Pharmaceutical Co. Ltd. are distributed in the United States by Prinston Pharmaceuticals dba Solco Healthcare, LLC.[3]

34. Defendant Huahai US Inc. ("Huahai US") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Huahai US is the wholly-owned subsidiary of ZHP. Huahai US "focus[es] on the sales and marketing of [ZHP's] APIs and Intermediates."[4] At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States. Defendant Huahai US Inc. is a subsidiary of ZHP.

35. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is a Delaware corporation with its principal place of business located at 2002 Eastpark Blvd.,

[3] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm;
[4] Huahai US, HOMEPAGE, https://www.huahaius.com/index.html (last accessed Apr. 5, 2019).

Cranbury, New Jersey 08512. Defendant Prinston is a majority-owned subsidiary of ZHP. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States. Solco Healthcare U.S., LLC is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical Co, Ltd. Defendant Prinston Pharmaceutical, Inc. manufactured ICDs using the API manufactured by ZHP.

36. Defendant Solco Healthcare US, LLC ("Solco") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Solco is a wholly-owned subsidiary of Prinston and ZHP. At all times material to this case, Solco has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States.

ii. Aurobindo Pharma, LTD. and Related Defendants

37. Defendant Aurobindo Pharma, Ltd. ("Aurobindo") is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs throughout the United States. Aurobindo supplies active pharmaceutical ingredients ("API"), including Irbesartan API, to United States manufacturers, who in turn produce finished product, with the expectation and actual knowledge that its API will be purchased and/or used in other drug products purchased throughout the United States.

38. Defendant Aurobindo Pharma USA Inc. is a company, with its principal place of business located at 279 Princeton Hightstown Road East Windsor, NJ 08520. Aurobindo Pharma USA Inc. is the wholly owned subsidiary of Aurobindo. At all times material to this case, Aurobindo Pharma USA Inc. has been engaged in the manufacture, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs in the United States.

39. Defendant Aurolife Pharma, LLC ("Aurolife") is a Delaware limited liability company with its principal place of business at 2400 US- 130, North, Dayton, New Jersey 08810. It is a wholly owned subsidiary of Aurobindo USA. At all times material to this case, Aurolife has been engaged in the manufacturing, sale, and distribution of ICDs in the United States. Collectively Aurobindo, Aurobindo Pharma USA Inc. and Aurolife will be referred to as the "Aurobindo Defendants" in this Complaint.

40. ScieGen Pharmaceuticals Inc U.S. ("ScieGen") is corporation, with its principal place of business at 89 Arkay Drive Hauppauge, NY 11788. ScieGen is a "fast growing generic pharmaceutical company" whose "core business is in the area of Development, manufacturing, marketing and Distribution of high quality and cost effective generic pharmaceutical products."

41. At all times material to this case, ScieGen has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic Irbesartan-containing drugs ("ICDs").

42. SciGen Pharmaceuticals Inc., U.S. Supplied Irbestartan to Westminster Pharmaceuticals and Golden State Medical Supply Inc.

43. Westminster Pharmaceuticals ("Westminster") is a corporation, with its principal place of business at 1321 Murfreesboro Pike, Suite 607, Nashville, TN 37217. At all times material to this case, Westminster has engaged in the manufacturing, sale, and distribution of contaminated,

adulterated, and/or misbranded generic ICDs in the United States, including the state of New Jersey.

44. Golden State Medical Supply ("Golden State") is a corporation, with its principal place of business at 5187 Camino Ruiz Camarillo, CA 93012. At all times material to this case, Golden State has engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs in the United States, including the state of New Jersey.

iii. Pharmacy Defendants

a. CVS Health

45. Defendant CVS Health Corporation ("CVS Health") is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island.

46. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

47. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment "provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance exchanges and private

health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States."

48. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

49. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

50. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

51. In 2014, CVS Health and wholesaler Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the valsartan-containing drugs purchased by CVS Health were acquired through this joint venture with Cardinal.

52. Upon information and belief, Defendant CVS Health sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

b. Walgreen Co.

53. Defendant Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015.

54. Upon information and belief, Defendant Walgreens Co. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

c. Walgreens Boots Alliance, Inc.

55. Walgreens Boots Alliance, Inc. is the parent Corporation of Defendant Walgreen Co.

56. Walgreens Boots Alliance, Inc. is Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

57. Walgreen Co. and Walgreens Boots Alliance, Inc. are collectively referred to within this Complaint as "Walgreens."

58. Walgreens is one of the retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states including the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five 5 miles of a store location. In addition, Walgreens recently purchased an additional 1,932 store locations from rival Rite Aid Corporation, further consolidating the industry. Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for prescription sales. Walgreens accounts for nearly 20% of the U.S. market for retail prescription drug sales.

59. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

60. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy. Upon information and belief, Defendant Walgreens sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

d. OptumRx

61. Defendant OptumRx is a Minnesota corporation, with its principal place of business at 2300 Main Street, Irvine, CA 92614.[5]

62. Defendant Optum Rx sold LCDs directly to Plaintiffs.

63. Upon information and belief, Defendant Optum Rx sold thousands of the adulterated and/or misbranded LCDs directly to U.S. consumers such as Plaintiffs.

e. Optum, Inc.

64. Defendant Optum, Inc. is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[6]

65. Upon information and belief, Defendant Optum Rx is a wholly owned subsidiary of Defendant Optum, Inc.

66. Upon information and belief, Defendant Optum Rx, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

f. UnitedHealth Group

67. Defendant UnitedHealth Group is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[7]

68. Upon information and belief, Defendant Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group.

69. Upon information and belief, Defendant United Health Group, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

[5] https://www.optumrx.com/public/information-center/public-contact-us
[6] https://www.optum.com/contact.html
[7] https://www.optum.com/contact.html

g. Wal-Mart, Inc.

70. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

71. Upon information and belief, Defendant Wal-Mart, Inc. (including Sam's Club) sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

iv. Wholesaler Defendants

72. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

73. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

74. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

75. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

a. Cardinal Health, Inc.

76. As mentioned above, Defendant Cardinal Health, Inc. is a corporation, with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.[8]

b. McKesson Corporation

77. Upon information and belief, Defendant McKesson Corporation is a Delaware corporation with its principal place of business located at 6535 North State Highway 161, Irving, Texas 75039.

c. AmerisourceBergen Corporation

78. Defendant AmerisourceBergen Corp. is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087.

v. Doe Defendants

79. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of DOES 1 through 100, inclusive, are unknown to Plaintiffs at this time, who therefore sue defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiffs for the acts and omissions alleged herein below, and the resulting injuries to Plaintiffs, and damages sustained by the Plaintiffs. Plaintiffs will amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

80. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE Defendants, and each of them, and at all said times, each

[8] https://www.theharvarddruggroup.com/shop/contact/index

Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

III. JURISDICTION AND VENUE

81. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

82. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

83. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because Defendants reside in this District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Prescription Drug Reimbursement

84. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

85. Pharmaceutical manufacturers produce drugs which they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

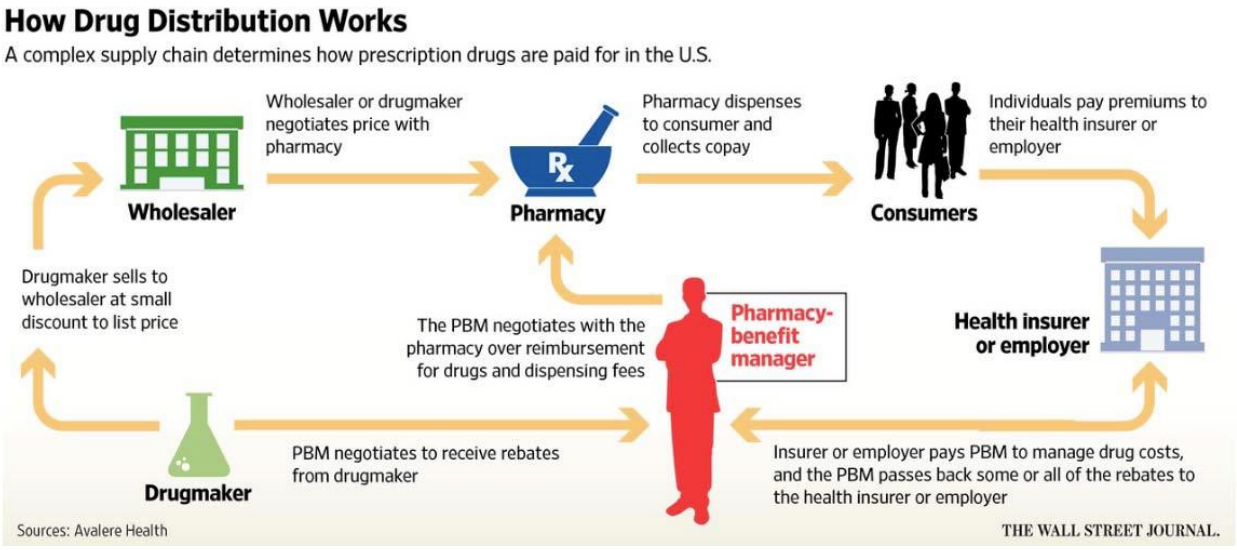
86. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing generic drugs, such as LCDs, on the TPPs' formularies.

87. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are bioequivalent or otherwise the same as their RLD counterparts. As is the case with all generic drugs, TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these generic drugs, such as the Defendants' LCDs, comply with their respective ANDAs, which state that the generic drugs are bioequivalent to their respective branded drug. Thus, the TPPs permitted the LCDs to be included on their formularies based on the Defendants' misrepresentations that their LCDs were bioequivalent to brand-named Diovan, complied with all cGMPs, and were safe for consumption.

88. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that the drug will be purchased by plan beneficiaries in lieu of a more expensive alternative, and vice versa. As such, higher formulary placement increases

the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

89. The following chart, published by the Wall Street Journal, broadly illustrates the pharmaceutical supply chain:[9]



90. When a patient presents his/her prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then cumulate those individual reimbursements and present them to TPPs for payment.

B. <u>Generic Drugs Must Be Chemically The Same As Branded Drug Equivalents</u>

91. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate

[9] Joseph Walker, Drugmakers Point Finger at Middlemen for Rising Drug Prices, WALL ST. J. (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed June 11, 2019).

bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[10]

92. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[11]

93. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

[10] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last accessed June 5, 2019) (emphasis in original).
[11]https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm.

94. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[12]

95. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[13]

C. Adulterated or Misbranded Drugs

96. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[14]

97. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[15]

98. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[16]

99. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[17]

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity

[12] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[13] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[14] 21 U.S.C. § 331(g).
[15] 21 U.S.C. § 331(a).
[16] 21 U.S.C. § 331(c).
[17] 21 U.S.C. § 351(a)(2)(A).

and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[18]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[19]

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[20]

100. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[21]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[22]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[23]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such

[18] 21 U.S.C. § 351(a)(2)(B).
[19] 21 U.S.C. § 351(b).
[20] 21 U.S.C. § 351(d).
[21] 21 U.S.C. § 352(a)(1).
[22] 21 U.S.C. § 352(c).
[23] 21 U.S.C. § 352(e)(1)(A)(ii)

manner and form, as are necessary for the protection of users. …"[24]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[25]

f. "if it is an imitation of another drug;"[26]

g. "if it is offered for sale under the name of another drug."[27]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[28]

i. If the drug is advertised incorrectly in any manner;[29] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[30]

101. As articulated in this Complaint, Defendants' unapproved LCDs were adulterated and/or misbranded in violation of all of the above-cited reasons.

D. Irbesartan Medications Are Recalled By The FDA Due To Presence Of Nitrosamines

102. The medication in question in this case is a drug that Defendants marketed and sold under the name "irbesartan."

[24] 21 U.S.C. § 352(f).
[25] 21 U.S.C. § 352(g).
[26] 21 U.S.C. § 352(i)(2).
[27] 21 U.S.C. § 352(i)(3).
[28] 21 U.S.C. § 352(j).
[29] 21 U.S.C. § 352(n).
[30] 21 U.S.C. § 352(p).

103. Irbesartan is a generic version of the brand-name medication Avapro®, and irbesartan with hydrochlorothiazide (HCTZ) is a generic version of Avalide®.

104. Irbesartan is used to treat high blood pressure and heart failure, and to improve a patient's chances of living longer after a heart attack.

105. Irbesartan is classified as an angiotensin receptor blocker (ARB) that is selective for the type II angiotensin receptor. It works by relaxing blood vessels so that blood can flow more easily, thereby lowering blood pressure.

106. Irbesartan can be sold by itself or as a single pill which combines irbesartan with HCTZ.

107. The drug binds to angiotensin type II receptors (AT1), working as an antagonist.

108. The patents for Avapro and Avalide expired in March 2012.[31]

109. Shortly after the patents for Avapro and Avalide expired, the FDA began to approve generic versions of the drugs.

110. Due to manufacturing defects in generic formulations of irbesartan, the ICDs became contaminated with nitrosamines, specifically NDEA.

1. NDEA

111. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[32]

112. NDEA is classified as a probable human carcinogen and a known animal carcinogen.[33]

[31] https://www.fiercepharma.com/special-report/avapro.
[32] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[33] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; *see also* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.

113. NDEA is an even more potent carcinogen than NDMA, which was the nitrosamine contaminant found in valsartan-containing medications.[34]

114. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

115. Hematological effects were also reported in animal studies.[35]

116. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[36]

117. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[37]

118. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[38]

119. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[39]

2. U.S. Irbesartan Recalls

120. Predating the irbesartan recalls were a wave of valsartan recalls. Valsartan is another ARB medication, in the same family of medications as losartan.

[34] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm
[35] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[36] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[37] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[38] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[39] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.

121. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[40] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[41]

122. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow.

123. On August 9, 2018, FDA announced that it was expending the recall to include valsartan-containing products manufactured by another API manufacturers, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained unacceptable levels of NDMA.[42] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[43]

124. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall notices also stated that the recalls related to unexpired valsartan-containing products.[44]

125. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect

[40] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[41] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[42] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[43] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[44] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."[45]

126. The first irbesartan recall was announced on October 26, 2018, wherein Defendant Aurobindo Pharma Limited announced a recall of 22 batches of irbesartan API due to the presence of NDEA. The recall notice noted that NDEA "has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC)."[46] The 22 "batches of Irbesartan drug substance were supplied to ScieGen Pharmaceuticals Inc., U.S. for the manufacturing of finished Irbesartan drug product."[47] Patients were instructed to contact their physicians or pharmacists regarding alternative treatment options.[48]

127. Next, on October 30, 2018, Defendant ScieGen Pharmaceuticals, Inc. announced a voluntary recall of its irbesartan tablets due to the presence of NDEA.[49] Sciegen reported that NDEA was "contained in the API Irbesartan, USP manufactured by Aurobindo Pharma Limited."[50] Patients were instructed to "return the effected medication to their pharmacy."[51]

128. Later, on January 18, 2019, Prinston Pharmaceutical Inc., dba Solco Healthcare LLC voluntarily recalled one lot of irbesartan and seven lots of irbesartan HCTZ due to presence of NDEA.[52] Defendant Prinston explained that the recalled lots contained NDEA "above the

---

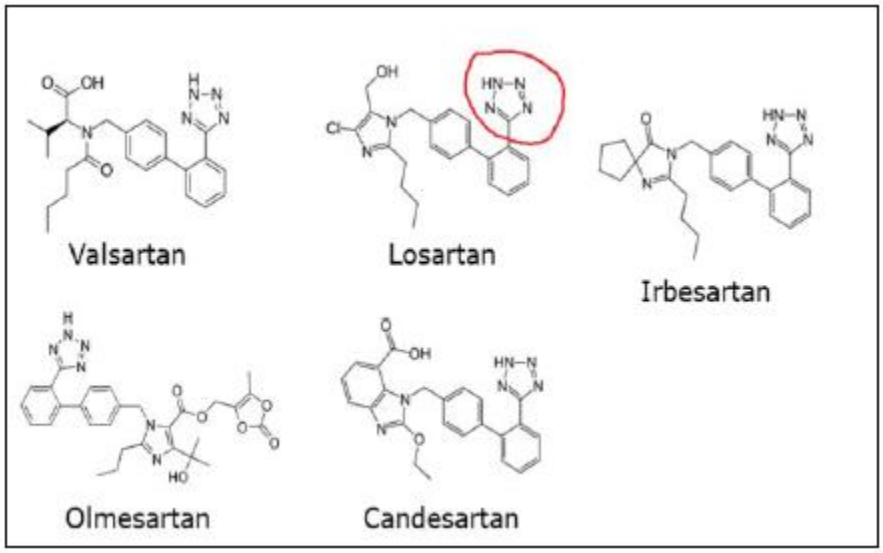
[45] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sciegen-pharmaceuticals-inc-issues-voluntary-nationwide-recall-irbesartan-tablets-usp-75-mg-150-mg (last visited 1/13/21).
[50] *Id.*
[51] *Id.*
[52] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-irbesartan-and-irbesartan-hctz (last visited 1/13/21).

acceptable daily intake levels released by the FDA."[53] Patients were advised to contact their pharmacists or physicians regarding alternative treatment options.[54] The recall notice further explained that the NDEA impurity was "found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals."[55]

E. Formation Of Nitrosamines In The ICDs

129. The nitrosamines at issue in this case are considered genotoxic compounds, as they all contain nitroso groups, which are gene-mutating groups.[56]

130. N-nitrosamines are formed at the tetrazole ring present in ARB medications, including valsartan, losartan, and irbesartan. The tetrazole ring is visually depicted in the following diagram[57]:

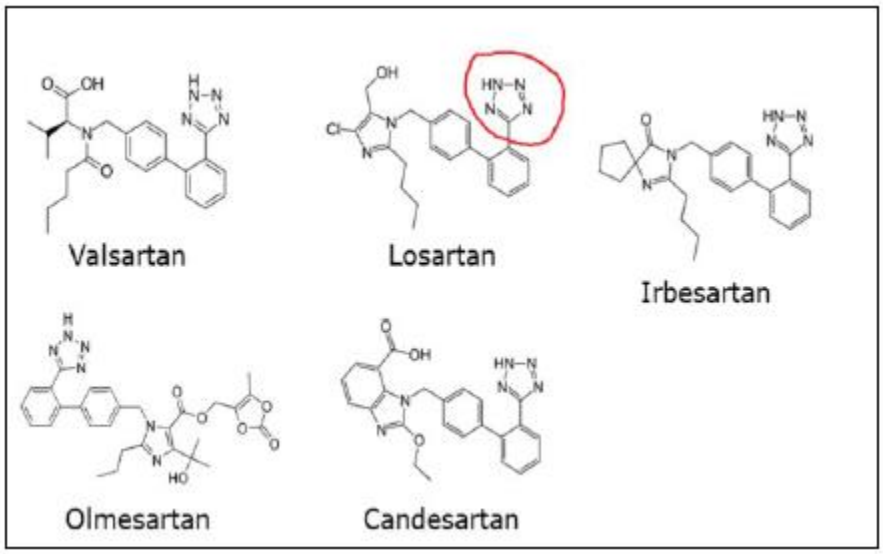


[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[57] Committee for Medicinal Products for Human Use, Assessment Report Article 31 Angiotensin-II-Receptor Antagonists (sartans) Containing a Tetrazole Group, at 3-4 (European Medicines Agency 2019).

131. N-nitrosamines are formed as part of the synthetic process or through introduction of N-nitrosamines through use of recovered solvents.

132. As to the synthetic process, "formation of N-nitrosamines is only possible in the presence of a secondary or tertiary amine and nitrite, usually under acidic reaction conditions."[58]

133. NDMA is derived from the decomposition of dimethylformamide (DMF) at high temperatures to dimethylamine (DMA). DMA acts as the secondary amine leading to formation of NDMA, as shown in the following diagram:

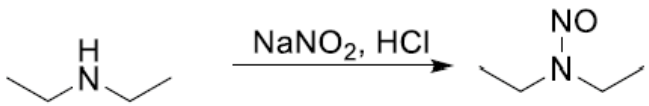


134. DMA may also be present as an impurity in DMF as it is a precursor in the industrial DMF synthetic process, which can then lead to formation of NDMA in the ARB drugs. DMA "may also be a degradant formed during storage of the solvent, potentially present as the formate salt."[59]

135. NDEA is "generated from diethylamine (DEA) by analogy to the formation of NDMA from DMA," as depicted in the following diagram[60]:

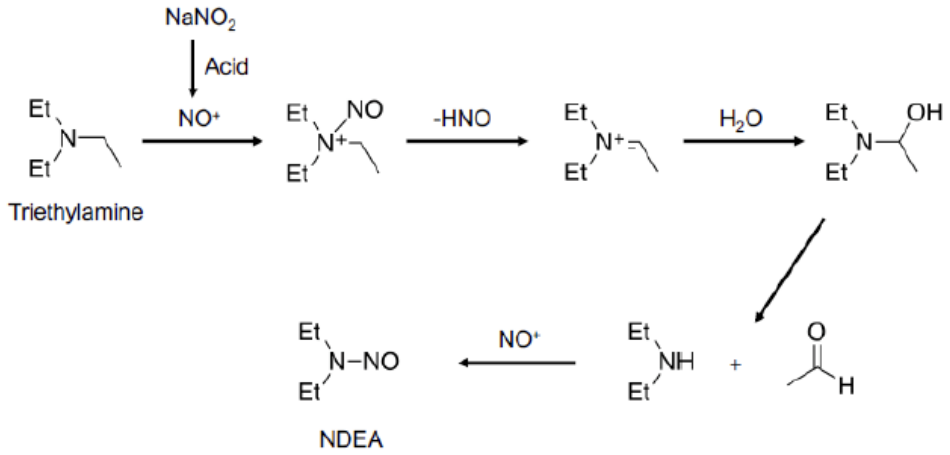
[58] *Id.* at 5.
[59] *Id.*
[60] *Id.*

Fig.: 3 General reaction scheme for formation of NDEA from diethylamine



136. Alternatively, "direct nitrosation of TEA may occur via a nitrosoiminium ion, resulting in the generation of an aldehyde and a secondary amine, which reacts with further nitrous acid to form a nitrosamine."[61]

Fig. 4: Nitrosative cleavage of TEA to DEA followed by nitrosation to NDEA



137. Upon information and belief, the nitrosamine contamination in the ICDs is also the result of the API Manufacturer Defendants utilizing recycled or recovered solvents during the manufacture of the Active Pharmaceutical Ingredient ("API").

138. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[62]

F. The Drugs Ingested By Plaintiffs Were Not Irbesartan, But New, Unapproved ICDs Not Of The Same Quality

139. The FDA's website provides the definition for a drug:

The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA

[61] *Id.* at 6.
[62] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

> regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[63]

140. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[64]

141. NDEA has the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDEA is, by definition, an active ingredient in a drug.

142. FDA further requires that whenever a new active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[65]

---

[63] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

[64] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3. (last visited 1/11/21).

[65] See 21 C.F.R. § 310.3(h).

143. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject ICDs) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

144. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[66]

145. Because the ICDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

146. The inclusion of an additional active ingredient (NDEA), and potentially other deviations from Defendants' ANDA approvals rendered Defendants' ICDs of a lesser quality than FDA-approved generic irbesartan.

147. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

G. Defendants Made False Statements In The Labeling Of Their ICDs

148. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[67] and conform to requirements governing the appearance of the label.[68]

[66] See generally https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false (last accessed June 6, 2019).
[67] 21 C.F.R. § 201.5.
[68] 21 C.F.R. § 801.15.

149. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[69] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

150. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[70]

151. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[71]

152. Because NDEA was not disclosed by Defendants as an ingredient in the ICDs ingested by Plaintiffs, the subject drugs were misbranded.

153. In addition, by referring to their drugs as "irbesartan" or "irbesartan HCTZ" Defendants were making false statements regarding their ICDs.

154. It is unlawful to introduce a misbranded drug into interstate commerce.[72] Thus, the ICDs ingested by individual Plaintiffs were unlawfully distributed and sold.

H. <u>The Generic Drug Supply Chain In The United States</u>

155. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

156. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to

[69] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[70] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[71] 21 C.F.R. § 201.6; 201.10.
[72] 21 U.S.C. § 331(a).

other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

157. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

158. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

I. Background On Current Good Manufacturing Practices ("cGMPs")

159. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

160. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

161. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F);

packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

162. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

163. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

164. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

165. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

166. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

167. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

J. The Generic Drug Approval Framework

168. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

169. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

170. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

171. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

1. *ANDA Applications Must Demonstrate Bioequivalence*

172. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

173. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

- a full description of the drug's substance, including its physical and chemical characteristics and stability; and
- the specifications necessary to ensure the identity strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

174. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

175. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

2. *ANDA Applications Must Provide Information About the Manufacturing Plants and Processes*

176. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

177. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

178. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process which ensures that the manufacturing process produces a dosage that meets product specifications.

3. *ANDA Applications Must Comply with cGMPs*

179. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPS.

180. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

4. *ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness*

181. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[73] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., irbesartan or irbesartan HCTZ), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

182. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

183. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding

[73] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."

brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

184. According to the FDA, there are at least twenty one ANDAs approved for generic Avapro, eighteen for generic Avalide.

a. Starting As Early As 2007, Defendants Were Actively Violating cGMPs In Their Foreign Manufacturing Facilities

185. For some time, Defendants have known that generic irbesartan drugs manufactured overseas were found or suspected to be less safe and effective than their branded equivalents or domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

186. Defendants' foreign manufacturing operations were no exception to this.

i. ZHP's Inadequate Manufacturing Processes

187. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and the European Union.

188. ZHP serves as a contract API manufacturer of numerous defendants' ARB drugs in this MDL (including for valsartan, and irbesartan) as set forth in this Complaint and the other operative Long Form Complaints in this MDL, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

189. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

190. On or about March 27-30, 2007, the FDA inspected ZHP's Xunqiao Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

191. The FDA inspected ZHP's same Xunqiao facility again on November 14-18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

192. On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its valsartan API at this Chuannan facility. That inspection resulted in the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter and investigation up to that point. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated." These findings were not made fully available to the public. However, this information was shared or available to ZHP's finished-dose manufacturers, as well as those Defendants further down the distribution chain.

193. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. . . . . To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts . . . . From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees results. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.' Specifically, this 85% was further broken down into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was provided to the consignee without a response and the consignee failed to respond but continued to purchase API from [ZHP]."[74]

194. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment" surrounding the facility. These manipulations of sampling were components of a pattern and practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA, NDEA, and NMBA.

195. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and there were black metallic particles in API batches.

[74] https://www.bloomberg.com/news/features/2019-01-30/chinese-heart-drug-valsartan-recall-shows-fda-inspection-limits.

196. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. . . . . To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts . . . . From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees results. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.' Specifically, this 85% was further broken down into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was provided to the consignee without a response and the consignee failed to respond but continued to purchase API from [ZHP]."

197. On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of its Chuannan facility. The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated and/or misbranded within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

198. The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012.

199. ZHP claimed that it had followed "common industry practice." Importantly, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." The FDA "strongly" recommended that ZHP hire a cGMP consultant and referred ZHP to four guides on cGMPs.

200. On September 28, 2018, the FDA stopped allowing ZHP to deliver drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

201. After the recalls of ZHP's valsartan-containing drugs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at its Linhai City facilities contained NDMA levels hundreds of times in excess of the FDA's interim limits[75] of 96 ng/day or 0.3 ppm.[76] Specifically, valsartan-containing drugs manufactured at ZHP for ZHP's subsidiary Prinston Pharmaceutical contained NDMA levels of between 15,180 and 16,300 ng, while Valsartan HCT manufactured at ZHP contained NDMA levels of between 13,180 and 20,190 ng.[77]

202. In addition, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at ZHP's Linhai City facilities for Torrent Pharmaceuticals contained NDEA levels upwards of fifty times in excess of the FDA's interim limits of 26.5 ng/day or 0.083 ppm. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent

[75] To be clear, ZHP's irbesartan products should not contain any NDEA.
[76] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed June 5, 2019).
[77] *Id.*

Pharmaceuticals' ICDs. ZHP valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng).

203. ZHP's irbesartan (sold through Prinston Pharmaceutical d/b/a Solco Healthcare US LLC, respectively) was also recalled for containing nitrosamine levels which rose above the FDA's acceptable limit.

204. By the time ZHP and its associated Defendants announced limited recalls of irbesartan, ZHP had already been placed on import alert.

205. Plaintiffs allege upon information and belief that more than] and one lot of irbesartan were contaminated with nitrosamines, and yet to date, more than a year after the announcement of these initial recalls, ZHP and Prinston have taken no additional action to release testing results or recall additional product.

ii. Aurobindo's Inadequate Manufacturing Processes

206. Aurobindo has API manufacturing facilities located in Hyderabad, Telangana, India.

207. Aurobindo manufactures at least some of its ARB drugs at these facilities, and Aurobindo Defendants thus have quality assurance obligations with respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

208. Aurobindo has a history of deviations from FDA's cGMP standards.

209. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]nvestigations are inadequate." The FDA explained that Aurobindo failed to initiate stability testing, and "[t]he deviation record contains field 'Number of previous deviations in this product/system.' This field requires previous deviations of the same product or deviation type to be reported, no previous deviations were reported in this field." Moreover, "[t]his is a repeat observation from the 2014 inspection."

210. Three months later, the FDA returned to Aurobindo's Hyderabad facilities and found four noteworthy manufacturing problems. First, "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Second, "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform [sic] to appropriate standards of identity, strength, quality and purity." Third, "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Fourth, the "use of instruments and recording devices not meeting established specifications was observed."

211. In October 2016, the FDA observed that Aurobindo's nearby Borpatla facility had inadequately validated equipment cleaning procedures.

212. In April 2017, the FDA observed that the manufacturing equipment in Aurobindo's Hyderabad facilities "is not always maintained to achieve its intended purposes." "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." "[C]orrective and preventative actions (CAPAs), identified and initiated because of out of specifications (OOS) laboratory investigations, do not correlate to the identified root cause. In certain cases, CAPAs are not initiated at all." "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." "Appropriate controls are not exercised over computers or related systems to assure that changes

in master production and control records or other records are instituted only by authorized personnel." "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established."

213. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second, "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

214. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions." Second, "[e]quipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." Third, "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." Fourth, "[b]uildings used in manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds[,] insects, and other vermin." Fifth, "[p]rocedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance." Sixth, "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions." Seventh, the

"statistical quality control criteria fail to include appropriate acceptance levels and rejection levels." Eighth, "[e]stablished laboratory control mechanisms are not followed and documented at the time of performance." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."

215. In October 2018, the European Medicines Agency banned Aurobindo from selling irbesartan in the European Union, following recalls of some lots of the API made by Aurobindo.[78]

216. It is clear Aurobindo has made no efforts at correct any of the previously identified errors, and continues to engage in grossly inadequate manufacturing processes. During an inspection *one month ago this year* (May, 2019), an investigator made note of a panoply of serious issues which called the integrity of the API manufacturing operations into question.

217. For example, in determining that the Medchal, Telangaga facility was not following quality control measures, and likewise did not have quality control procedures in place, the investigator observed "loose handwritten notebooks with what appears to be laboratory test data results."

218. Additionally, while Aurobindo claimed to have performed tests and quality control activities on API as a result of the FDA's investigation into adulterated ICDs, during the inspection, the investigator found that the API was not being adequately retained and/or

[78] https://www.ema.europa.eu/en/news/eu-authorities-take-further-action-ongoing-review-sartans-zheijiang-huahai-placed-under-increased.

appropriately identified, calling Aurobindo's testing of this API into question. More troubling, this API sampled and analyzed by the investigator was to set to be shipped into the United States.

219. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "incomplete data." The testing systems also allowed certain employees to "verify incomplete data in raw data file." The investigator found that the quality control reviewers attested to practices which "contradict actual review practices performed by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data.

220. The investigator also noted that in addition to all of the gross processing and data integrity issues, *even the building itself* did not have the "suitable construction to facility cleaning, maintenance and proper operations." The investigator noted that in a stability sample storage room, they observed a "PVC pipe connected to an air conditioner unit on one end, and paced in a blue plastic bucket on the other end with approximate 50% of the bucket filled with condensate water." There were four other similar setups in other critical rooms in the facility.

221. On June 20, 2019, Aurobindo received yet another warning letter from the FDA which stemmed from FDA's inspection of one of Aurobindo's manufacturing facilities in India that took place from February 4-9, 2019.[79]

222. In this letter, FDA cited Aurobindo for "significant deviations" from cGMPs for active pharmaceutical ingredients and stated that its API was adulterated as a result of these deviations. The letter further stated that Aurobindo's contaminated API was due to the use of

[79] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aurobindo-pharma-limited-577033-06202019.

recovered solvents, and while Aurobindo had stopped using solvents from the particular vendor that provided them, Aurobindo had not solved other important quality issues. Aurobindo was further cited for violations stemming from its failure to report changes to its methods and procedures.

223. After the recalls of Aurobindo's valsartan, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by Aurobindo contained NDEA exceedances well in excess of the FDA's interim limits[80] of 26.5 ng/day or 0.083 ppm.[81]

224. While testing results in the US for Aurobindo's ICDs are not readily available, information released by Health Canada shows that numerous batches of Aurobindo's ICDs tested contained unsafe levels of NDEA as high as 30.29 nanograms per tablet[82], which exceeded the FDA's interim limit of 26.5 nanograms per day.

K. Defendants Had Actual And/or Constructive Notice of NDEA Contamination Of Their Adulterated, Misbranded, And/Or Unapproved ICDs

225. The FDA has noted in connection with the ICD recalls that NDEA "has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."[83]

226. The FDA has further noted, in connection with the ICD recalls, that NDEA is a probable human carcinogen.[84]

---

[80] To be clear, Aurobindo's irbesartan products should not contain any NDEA.
[81] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed June 5, 2019).
[82] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html.
[83] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-tablets-usp (last visited 1/12/21).
[84] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm. (last visited 1/13/21).

227. As alleged above, the ICDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDEA.

228. NDEA is not an FDA-approved ingredient for brand-name Avapro® and Avalide®.

229. Moreover, none of Defendants' ICDs identify NDEA or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogens and are not approved to be included in irbesartan API or finished-dose products.

230. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

231. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

232. And as shown above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

233. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' ICDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their ICDs were adulterated and/or misbranded as early as 2012.

L. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic ICDs

234. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded ICDs.

1. *Warranties Common To All Manufacturer Defendants*

235. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[85] The Orange Book is a public document; Defendants sought and received the inclusion of their ICD products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic ICDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic ICDs were bioequivalent to their RLDs.

236. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book,

[85] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, at https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed June 5, 2019).

therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

237. Each Defendant's ICD(s) is/are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved ICD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers and TPPs of the "sameness" of their products to the ICD's RLD, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

238. By introducing their respective ICDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to end users and TPPs that their ICDs are in fact the same as and are therapeutically interchangeable with their RLDs. Much of the generic drugs supply chain, including the most critical components of that supply chain (end-user patients and reimbursing TPPs) rely on these representations and warranties.

239. In addition, each Defendant affirmatively misrepresented and warranted to consumers and TPPs through their websites, brochures, and other marketing or informational materials that their ICDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

240. The presence of nitrosamines in Defendants' ICDs: (1) renders Defendants' ICDs non-bioequivalent (*i.e.*, not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' ICDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in

Defendants' ICDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, or negligently failed to ensure their ICDs' labels and other advertising or marketing statements accurately conveyed information about their products.

241. The presence of nitrosamines in Defendants' ICDs and Defendants' serial and willful failures to comply with cGMPs and other shortcomings in Defendants' generic drug manufacturing processes have resulted in Defendants' ICDs being adulterated and/or misbranded compared to Defendants' representations and warranties.

242. At all relevant times, Defendants have also impliedly warranted that their ICDs were merchantable and fit for their ordinary purposes.

243. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, NDEA is not an FDA-approved ingredient in the ICDs. The presence of NDEA and other similar nitrosamines or impurities in Defendants' ICDs means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDEA in Defendants' ICDs results in Defendants' ICDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

244. For these and other reasons, Defendants' ICDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such ICDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

245. Adulterated, misbranded, and/or unapproved ICDs contaminated with cancer-causing compounds are essentially worthless. No reasonable consumer (including Plaintiffs)

would purchase (or reimburse for) these nitrosamine-laden ICDs. Nor could they, as an adulterated, misbranded, and/or unapproved ICDs cannot even be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, and/or unapproved ICDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved ICDs do not possess the same safety and efficacy profile as their branded equivalents. As such, the ICDs were not what they were supposed to be.

246. Moreover, every consumer (and every TPP's insured) who purchased and ingested a ICD, including Plaintiffs (or Plaintiffs' insureds), has been exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and subcellular levels, and may give rise to future potential health consequences.

247. The recalls were meant to quickly remove unsafe products from the market. While FDA advised patients to continue taking ICDs, it only did so because of the risks associated with untreated high blood pressure.

248. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

249. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. ICDs had no use and were discarded.

2. ZHP Defendants' Warranties

250. On its website (as it appeared in January 2019),[86] ZHP stated that it "has established an independent, strict and sound quality mangement [sic] system in accordance with

[86] ZHP completely changed its website sometime in February or March 2019.

GMP." ZHP further claims that it "ensure[s] that production is operated in accordance with GMP and product quality meets the required specifications," and that ZHP's "workshops of formulation are designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."

251. Huahai US assisted Prinston in obtaining approval of its ANDA for its ARB drugs.

252. Solco lists its ICDs as equivalent to Avapro and Avalide on its website.[87]

253. Furthermore, Solco states on the "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[88]

254. On the "Drug Safety" page of its website, Solco states that "Solco Healthcare is committed in providing . . . its patients with high quality, FDA-approved generic medications."[89]

3. Aurobindo Defendants' Warranties

255. Aurobindo's website states that it is "Committed to Quality and Safety."[90]

256. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[91] Aurobindo also "[s]eek[s] to attain the highest quality standards."[92]

---

[87] https://www.solcohealthcare.com/shop/products/page/4/.
[88] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last accessed Apr. 5, 2019).
[89] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Apr. 5, 2019).
[90] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited June 5, 2019).
[91] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last accessed June 5, 2019).
[92] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last accessed June 5, 2019).

257. Aurolife states, "The Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP compliant manufacturing facility with an investment of over US $50 million."[93]

4. ScieGen Pharmaceuticals Inc.'s Warranties

258. ScieGen's website lists its irbesartan tablets as the generic equivalent to Avapro.[94]

259. On its website, ScieGen states, "Our core business is in the areas of Development, Manufacturing, Marketing and Distribution of high quality and cost effective generic pharmaceutical products. ScieGen has robust product development pipeline and filed a couple of ANDA's. We aim to provide healthcare at economical prices to make this a healthier world to live in."[95]

5. Westminster Pharmaceuticals' Warranties

260. On its website, Westminster Pharmaceuticals warrants that it "provides high-quality and cost-effective generic pharmaceuticals…"[96]

261. The company's website further states, "We believe in access to high quality pharmaceuticals at affordable prices. Compliance is key. We don't cut corners, but rather have an effective methodology that allows us to acquire high-quality generic drugs within high-demand categories. Cut costs and offer your patients the best generic pharmaceuticals when you partner with Westminster."[97]

6. Golden State Medical Supply's Warranties

---

[93] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last accessed June 5, 2019).
[94] https://sciegenpharm.com/products/.
[95] https://sciegenpharm.com/about-us/.
[96] https://www.wprx.com/about
[97] https://www.wprx.com/retail-specialty-hospital-pharmacies.

262. Golden State Medical Supply (GSMS, Inc.) warrants to its customers as follows: "We are a pharmaceutical company that specializes in delivering high-quality affordable generics and unique packaging solutions for our customers. A foundation of core values, including innovation, integrity and quality have lead to the rapid growth of our company. We strive to make every day better than the last, valuing that our products and our services impact millions of lives."[98]

263. The company further states on its website, "GSMS is dedicated to ensuring the integrity of not only our products but also the integrity of the pharmaceutical supply chain. We have the capabilities to meet the safety, packaging, labeling, serialization, and distribution needs of our customers and the patients they serve."[99]

7. *Warranties Common to All Retail Pharmacy Defendants*

264. Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

265. By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments from are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy defendants warrant that prescription drugs they sell are of a standard quality.

[98] https://gsms.us/about-us/.
[99] https://gsms.us/about-us/.

266. On account of the existence of these strict liability implied warranties, most retail pharmacies secure indemnification from manufacturer defendants for breach of such warranties.

267. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

8. *Wholesale Distributor Defendants' Warranties*

268. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

9. *Repackager and Relabeler Defendants' Warranties*

269. By selling drugs in the stream of commerce, each repackager and relabeler defendant warrants that the generic drugs they sell are same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics.

270. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

M. Fraudulent Concealment And Tolling

271. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Defendants' generic ICDs.

272. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid

disclosing their knowledge of their and other Defendants' cGMP violations with respect to their ICDs, and of the fact that their ICDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

273. For instance, no Defendant revealed to the public that their ICDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in December 2018.

274. Each Defendant continued to represent and warrant that their generic ICDs were the same as and therapeutically interchangeable with their RLDs.

275. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for their ICDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

276. As a result of each Defendants' affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

V. CLASS ACTION ALLEGATIONS

277. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

> All individuals and entities in the United States and its territories and possessions who paid any amount of money for an irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.

278. The Nationwide Class has two sub-classes:

> All consumers in the United States and its territories and possessions who paid any amount of money for an irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.
>
> All TPPs in the United States and its territories and possessions that paid any amount of money for an irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant.

279. Plaintiffs allege additional sub-classes for all individuals and TPPs in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment – who paid any amount of money out of pocket for an irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant. These include but are not limited to the following:

a. Plaintiffs Bacharach and Annis seek to represent a Florida sub-class and/or subclass(es) of states with similar applicable laws to Florida.

b. Plaintiff Wineinger seeks to represent an Indiana sub-class and/or subclass(es) of states with similar applicable laws to Indiana.

c. Plaintiff Johnson seeks to represent a New York sub-class and/or subclass(es) of states with similar applicable laws to New York.

d. Plaintiff Miller seeks to represent a Maryland sub-class and/or subclass(es) of states with similar applicable laws to Maryland.

e. Plaintiff Westry seeks to represent an Alabama sub-class and/or subclass(es) of states with similar applicable laws to Alabama.

f. Plaintiffs reserve the right to amend this Complaint to add additional class representatives as appropriate or necessary for additional sub-classes for one or more states.

280. Collectively, the foregoing Nationwide Class and its sub-classes are referred to as the "Class."

281. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

282. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

283. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

284. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of irbesartan consumers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

285. **Commonality**: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding their generic ICDs;

b. Whether each Defendant's ICDs were in fact the same as their RLDs consistent with such express or implied warranties;

c. Whether each Defendant's ICDs were contaminated with NDEA or similar contaminants;

d. Whether each Defendant's ICDs containing NDEA or similar contaminants were adulterated and/or misbranded;

e. Whether Defendants violated cGMPs regarding the manufacture of their ICDs;

f. Whether each Defendant falsely claimed that its ICDs were the same as their RLDs and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiffs' and Class Members' causes of action accrued; and

k. Whether Defendants fraudulently concealed Plaintiffs' and Class Members' causes of action.

286. **Typicality**: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

287. **Adequacy of Representation**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiffs and their counsel will

fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

288. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

289. The requirements of Rule 23(b)(3) are met. The common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

290. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

291. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

292. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs and the other Class members purchased the ICDs. The terms of the contract include the promises and affirmations of fact made by Defendants on the ICDs' packaging and through marketing and advertising, including that the product would be bioequivalent to the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

293. Each Defendant expressly warranted that its ICDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

294. Each Defendant sold ICDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

295. Each Defendant's ICDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

296. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal.

Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.\

297. At the time that each Defendant marketed and sold its ICDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members including but not limited to express representations made in referring to their ICDs as irbesartan or irbesartan HCTZ.

298. Each Defendant breached its express warranties with respect to its ICDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

299. Plaintiffs and each member of the Class would not have purchased the ICDs had they known these drugs were not the same as the RLD, did not contain the same ingredients, did not have the same safety and efficacy profile of the RLD, and contained NDEA.

300. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the ICDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

SECOND CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

301. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

302. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

303. Each Defendant expressly warranted that its ICDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

304. Each Defendant sold ICDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

305. Each Defendant's ICDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

306. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

307. At the time that each Defendant marketed and sold its ICDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the

same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members, including but not limited to express representations made in referring to their ICDs as irbesartan or irbesartan HCTZ.

308. Each Defendant breached its express warranties with respect to its ICDs as they were not of merchantable quality, were not fit for its ordinary purpose, and did not comply with cGMP and were adulterated and misbranded.

309. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' ICDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

310. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

311. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

312. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code.

§ 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

313. Each Defendant was a merchant within the meaning of the above statutes.

314. Each Defendant's ICDs constituted "goods" or the equivalent within the meaning of the above statutes.

315. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit ICDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

316. Each Defendant knew or should have known that its ICDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive

knowledge), and impliedly warranted that their ICDs were of merchantable quality and fit for that purpose.

317. Each Defendant breached its implied warranty because each Defendant's ICDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

318. Plaintiffs and other Class members purchased the ICDs in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

319. The ICDs were not altered by Plaintiffs or Class members.

320. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' ICDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

321. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

322. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

323. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314;

Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq*.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

324. Each Defendant was a merchant within the meaning of the above statutes.

325. Each Defendant's ICDs constituted "goods" or the equivalent within the meaning of the above statutes.

326. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit ICDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

327. Each Defendant knew or should have known that its ICDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that same was of merchantable quality and fit for that purpose.

328. Each Defendant breached its implied warranty because each Defendant's ICDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

329. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' ICDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FIFTH CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

330. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

331. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

332. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

333. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

334. Each Defendant expressly or impliedly warranted their ICDs as alleged in the First and Second Causes of Action.

335. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

336. No Defendant has acted on the opportunity to cure its failure with respected to its warranted ICDs.

337. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SIXTH CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

338. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

339. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

340. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

341. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

342. Each Defendant expressly or impliedly warranted their ICDs as alleged in the First and Second Causes of Action.

343. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

344. No Defendant has acted on the opportunity to cure its failure with respected to its warranted ICDs.

345. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SEVENTH CAUSE OF ACTION
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

346. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

347. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

348. Defendants affirmatively misrepresented material facts including, *inter alia*, that their ICDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

349. Defendants omitted material facts including, *inter alia*, that their ICDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

350. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' ICDs – products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMPs and/or were adulterated and/or misbranded. Plaintiffs and other Class Members would not have purchased Defendants' ICDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' ICDs had they known the truth because Defendants' ICDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

351. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

352. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' ICDs.

353. Defendants' misrepresentations and omissions were material.

354. Defendants' actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

355. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' ICDs.

356. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' ICDs.

357. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' ICDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

358. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

EIGHTH CAUSE OF ACTION
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

359. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

360. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

361. Defendants affirmatively misrepresented material facts including, *inter alia*, that their ICDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

362. Defendants omitted material facts including, *inter alia*, that their ICDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

363. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' ICDs – product which Defendants knew or should have known was not therapeutically equivalent to their RLDs and did not comply with GMPs and were adulterated and misbranded. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' ICDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' ICDs had they known the truth because Defendants' ICDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

364. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

365. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' ICDs.

366. Defendants' misrepresentations and omissions were material.

367. Defendants actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

368. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' ICDs.

369. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' ICDs.

370. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical

misrepresentations and omissions were communicated to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' ICDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

371. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

372. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

373. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

374. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its ICDs.

375. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its ICDs.

376. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its ICDs.

377. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

378. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that

its misrepresentations and omissions would induce Class members to make purchases of each Defendant's ICDs.

379. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

380. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for ICDs.

381. Each Defendant intended its misrepresentations or omissions to induce Plaintiffs and Class members to make purchases of ICDs, or had reckless disregard for same.

382. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendants' ICDs.

383. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

384. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

TENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

385. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

386. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

387. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its ICDs.

388. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its ICDs.

389. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its ICDs.

390. Each Defendant's statements were false at the time the misrepresentations were made (or at the time of the omissions).

391. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's ICDs.

392. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

393. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for ICDs.

394. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of ICDs, or had reckless disregard for whether they would do so.

395. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have purchased Defendants' ICDs.

396. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

397. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

ELEVENTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

398. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

399. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

400. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vermont's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

401. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

402. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

403. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

TWELFTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

404. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

405. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

406. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vermont's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

407. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

408. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

409. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

THIRTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

410. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

411. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

412. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' ICDs.

413. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' ICDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

414. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' ICDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

415. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FOURTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

416. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

417. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

418. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' ICDs.

419. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' ICDs were adulterated and/or misbranded, their distribution and sale in the United States was illegal.

420. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' ICDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

421. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FIFTEENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

422. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

423. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

424. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its ICDs.

425. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the ICDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

426. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of ICDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its ICDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

427. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own ICDs. Each Defendant knew that ignoring the manufacturing issues surrounding its ICDs would damage Plaintiffs and the Class and increase its own profits.

428. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its ICDs complied with cGMPs and was not adulterated or misbranded.

429. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its ICDs.

430. Each Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

431. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SIXTEENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

432. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

433. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

434. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its ICDs.

435. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the ICDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

436. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of ICDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its ICDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

437. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own ICDs. Each Defendant knew that ignoring the manufacturing issues surrounding its ICDs would damage Plaintiffs and the Class and increase its own profits.

438. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its ICDs complied with cGMPs and were not adulterated or misbranded.

439. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its ICDs.

440. Each Defendant breached the duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

441. As a direct and proximate result of each Defendant's negligent, and possibly grossly negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SEVENTEENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

442. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

443. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

444. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its ICDs.

445. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the ICDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

446. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

447. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

448. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

449. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

EIGHTEENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

450. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

451. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

452. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its ICDs.

453. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the ICDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

454. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted or adheres to federal cGMP and adulteration standards.

455. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

456. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

457. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

1) An order certifying this action as a class action;
2) An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;
3) A declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;
4) An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;
5) Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the ICDs; the costs to replace or return ICDs because of recalls; and/or the increases in the amounts paid for non-adulterated, non-misbranded, ICDs in the wake of the recalls;
6) An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

7) An award of statutory penalties to the extent available;

8) Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

9) Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: 1/15/2021

Respectfully Submitted,

/s/ Ruben Honik
Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone (215) 985-9177
rhonik@golombhonik.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

/s/ Conlee Whiteley
Conlee Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel